

REMARKS

Claims 14 and 15 have been cancelled herein. Claim 16 has been amended. Support for the amendment to Claim 16 can be found throughout the specification, including the claims as originally filed. New Claim 31 has been added. Support for new Claim 31 can be found throughout the specification, including paragraph [0019] in the application as published and Example 3. No new matter has been added.

Accordingly, Claims 16-28 and 31 are presently pending. In view of the amendments made herein and the remarks set forth below, reconsideration is respectfully requested.

Rejections Under 35 U.S.C. § 112

Claims 14-28 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. More specifically, Claims 14 and 15 are said to be vague and indefinite for failing to clearly recite what the formulation contains and failing to set forth the steps involved in the method or process. Claims 14 and 15 have been cancelled, thereby rendering the rejection moot.

Claims 16, 18, 26, 27 and 28 are said to be rendered vague and indefinite for not clearly describing how the administering step is performed. Applicants respectfully disagree with this rejection and note that it is standard claim practice to recite an “administering” step, which is then further defined in various dependent claims. Nevertheless, in order to further prosecution, Applicants have amended Claim 16 to recite the various methods by which the administering steps are performed.

Rejections Under 35 U.S.C. §101

Claims 14 and 15 are also rejected under 35 U.S.C. §101 as being an improper definition of a process. As mentioned above, Claims 14 and 15 have been cancelled, thereby rendering this rejection moot.

Rejections Under 35 U.S.C. §103

Claims 14-28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over newly cited Hipskind et al. (U.S. Patent No. 5,773,441). The examiner asserts that Hipskind teaches GHRP-6 comprising SEQ ID NO. 1. The examiner further asserts that elevation of growth hormone levels have been demonstrated to have significant therapeutic utility for disease states in humans. In addition, the examiner asserts that elevated growth hormone levels in animals has been shown to result in increased lean muscle mass. The examiner further asserts that GHRP-6 has been used in animal husbandry as an effective agent. In view of the forgoing, the examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize GHRP-6 for effecting growth hormone levels in fish.

Applicants respectfully traverse. Claim 16 has been amended to delete the element of stimulating growth. Accordingly, all that remains in Claim 16 is a method for stimulating resistance to diseases in fish and crustaceans. There is no disclosure in Hipskind that the administration of GHRP-6 would be successful in stimulating resistance to disease in fish and crustaceans. In addition, there is no teaching or suggestion in Hipskind that GHRP-6 would have any prophylactic effect on disease. Also, nothing in Hipskind makes the correlation between physical strength or lean muscle mass gained by administration of GHRP-6 and resistance to disease.

In addition, the examiner cites to column 2, line 48 of Hipskind for the disclosure that GHRP-6 are orally available. In fact, at column 2, line 48, Hipskind is referring to nonpeptidyl analogues of GHRP-6 that should be orally bioavailable. Accordingly, if anything, this portion of Hipskind suggests that GHRP-6 would not be orally bioavailable. This would be the implicit reason for researchers to develop the nonpeptidyl analogues. This disclosure of the metabolic instability of GHRP-6 therefore actually teaches away from the claimed method, especially Claim 17, which specifies administration of the GHRP-6 to the feed of the fish and crustaceans,

and Claim 20, which specifies administration of GHRP-6 by emersion. At column 1, lines 41-49 of Hipskind, the Applicants explain “the primary obstacle to the use of GRF as a direct supplement is its short life span in vivo. *L.A. Frohman, et al., Journal of Clinical Investigation, 78:906(1986)*. More potent and/or longer lasting GRF molecules are therefore desirable for the development of effective human therapeutic or animal husbandry agents.” Thus, one skilled in the art would not anticipate success by administering GHRP-6 by immersion or by addition to the feed of fish or crustaceans.

Similarly, the examiner relies heavily on the citation from column 3, line 63 of Hipskind, which discloses the compound suitable for animal husbandry, including fish. However, these again are the nonpeptidyl secretagogues of the invention in Hipskind. There is no disclosure in the Hipskind reference that GHRP-6 would be effective to stimulate resistance to diseases in fish and crustaceans.

Thus, upon careful review of Hipskind, it will be noted that Hipskind does not teach that fish are treatable with GHRP-6, Hipskind does not teach that GHRP-6 is an effective agent in animal husbandry. Hipskind does not teach that GHRP-6 is orally active, and Hipskind does not teach that GHRP-6 stimulates resistance to disease. Therefore, there is no teaching or suggestion in Hipskind that GHRP-6 would stimulate resistance to diseases in fish or crustaceans as set forth in the claims as presently amended.

In view of the forgoing, Applicants respectfully assert that one skilled in the art at the time of the invention would not have a reasonable expectation of success in performing the claimed methods, as amended. Therefore, withdrawal of the rejections under 35 U.S.C. §103 is respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, entry of the amendments and favorable consideration of the claims is respectfully requested. If the examiner has any questions or concerns regarding this amendment, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

/james f. harrington/
James F. Harrington
Registration No.: 44,741
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(516) 822-3550
JFH/jp